

REMARKS/ARGUMENTS

The present application has been reviewed in light of the Non-Final Office Action dated June 5, 2007. Claim 1 has been amended, without intending to abandon or to dedicate to the public any patentable subject matter. Accordingly, Claims 1-26, 28 and 29 and are now pending. As set forth herein, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

The Examiner has rejected Claims 1-16, 23, 28 and 29 under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 7,156,823 to Landau (Landau '823). Claims 17-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Landau '823 in view of United States Patent Application No. 2003/0093030 (Landau '030). Additionally, the Examiner has rejected Claims 24-26 under 35 U.S.C. § 103(a) as being unpatentable over Landau '823 in view of United States Patent No. 6,752,781 to Landau et al. (Landau '781).

Initially, the Applicant's Attorneys would like to thank the Examiner for the courtesies extended during the telephonic interview, which took place on October 3, 2007. The substance of the arguments made by the Applicant's Attorneys during the interview is summarized in the following remarks. During the interview, an agreement was reached with respect to claim amendments that would provided a patentable distinction over the cited references. In particular, the Examiner and the Applicant's Attorneys generally agreed that amended claims which include a recitation of a claim element that medicament is drawn in through the same nozzle which the medicament is later expelled, would provide a patentable distinction over the cited references.

The claimed invention is directed to a disposable gas-powered needle-free injection device having an axially-movable inner housing which can be used to draw in a desired dose of liquid medicament into the device ready for delivery into the patient. In the claimed invention, medicament is drawn into the nozzle through the nozzle outlet. Additionally, the claimed invention includes an inner housing located at least partly within an outer housing and a cooperating guide means disposed on the inner and outer housing. The cooperating guide means allow the inner housing to move away from the nozzle, which is formed on the outer housing. The movement of the inner housing away from the nozzle enables the drawing in of medicament.

Claim Rejections - 35 U.S.C. § 102(e)

The Examiner has rejected Claims 1-16, 23, 28 and 29 as being anticipated by '823. Landau '823 is directed to needle-free injection system that operates in connection with a pressurizing system. The device disclosed by Landau '823 includes a nozzle 30 having two separate fluid passageways. In particular, the nozzle 30 includes an inlet 42 for drawing in medicament, and an outlet 40 through which medicament is expelled during an injection. The nozzle 30 is disposed on a fluid cylinder 32, which is axially movable with respect to a piston cylinder 62/62a. Threads 80 facilitate the movement between these two cylinders. Additionally, the Landau '823 device includes a reciprocating structure 92 that facilitates movement of various components (*i.e.* the gas cylinder 72 and the piston cylinder 62/62a) with respect to an outer housing 26.

Landau '823 does not disclose a device in which medicament is drawn in through a fluid outlet. Claim 1 has been amended to further distinguish this aspect of claimed invention over Landau '823. In particular, Claim 1 has been amended to recite that medicament is drawn into the nozzle through the nozzle outlet. This is in sharp contrast to the Landau '823 device, which includes two separate fluid passageways in the nozzle 30. In particular, the Landau '823 device includes both a fluid inlet 42 and an outlet 40 in the nozzle 30. Therefore, Landau '832 does not teach, suggest or describe a device in which a medicament is drawn into the device through a nozzle outlet, and in which, in use, a piston and ram drive the medicament out of the nozzle outlet. Accordingly, Claim 1 and the claims dependent therefrom are not anticipated by Landau '823 for at least the reason that Landau '823 does not provide a nozzle as claimed.

Landau '823 also does not disclose cooperating guide means between an outer housing having a nozzle and an inner housing disposed at least partly within the outer housing. This combination of elements allows the inner housing to be axially movable away from the nozzle to enable medicament to be drawn in. This combination of elements and this axial movement are recited by Claim 1. It is respectfully submitted that regardless of which components of Landau '832 are designated as the "outer housing" and the "inner housing," Landau '823 does not disclose this combination of elements, as recited by Claim 1. In the following subsections, the

Examiner's attention is respectfully drawn to possible designations of components of Landau '823 as an "inner housing" and an "outer housing." The following subsections address at least those various designations asserted by the Examiner, both in the written Office Action and in the telephonic interview. After the following discussion, it will be appreciated that Landau '823 does not anticipate the above mentioned combination of elements. In particular, Landau '823 lacks cooperating guide means between an outer housing having a nozzle and an inner housing disposed at least partly within the outer housing.

Outer Housing 26 as "Outer Housing"

Piston Cylinder 62 or Gas Cylinder 72 as "Inner Housing"

In the Office Action, The Examiner has cited item 85 of Landau '823 as being an "outer housing." It is observed that the numeral 85 refers to "indicia" (Landau '823; col. 4, ln. 14), which is included on the surface of the fluid cylinder 32. During the interview which took place on October 3, 2007, the Examiner and the Applicant's Attorney's agreed that the labeling of indica 85 as an "outer housing" was made in error. Moreover, it was agreed that Landau '823 specifically recites an outer housing 26 (Landau '823; col. 3, lines 5-6).

With the outer housing 26 properly identified, it is initially noted that the outer housing 26 lacks cooperating guide means and a nozzle, both of which are recited in the outer housing of the claimed invention. Notwithstanding this, two possible candidates for the "inner housing" are the piston cylinder 62 and the gas cylinder 72 in Landau '823. While, the piston cylinder 62 and gas cylinder 72 are not themselves "selectively axially moveable away from the nozzle," the nozzle 40 could be considered to be selectively axially moveable away from the piston cylinder 62 and the gas cylinder 72 by rotation of the fluid cylinder 32. However, the device disclosed by Landau '823 still lacks "a cooperating guide means on said inner and outer housings," as recited by the claimed invention. In Landau '823, the threads 80 are between the fluid cylinder 32 and the piston cylinder 62, not between the outer housing 26 and "inner housings" (piston cylinder 62 or gas cylinder 72). Therefore, with the piston cylinder 62 or the gas cylinder 72 designated as the "inner housing," the Landau '823 device lacks "axial movement of the inner housing guided

by said cooperating guide means to enable a desired dose of medicament to be drawn into said nozzle," as recited by the claimed invention. Additionally, as noted above, the outer housing 26 of Landau '823 lacks cooperating guide means and a nozzle, as recited by the claimed invention.

Outer Housing 26 as "Outer Housing"

Fluid Cylinder 32 as "Inner Housing"

Additionally, with the outer housing 26 properly identified, an alternative possible candidate for the "inner housing" is the fluid cylinder 32 in Landau '823. It is noted that the fluid cylinder 32 is "located at least partly within the outer housing," and rotation of the fluid cylinder 32 using threads 80 moves the "inner housing" (fluid cylinder 32) axially with respect to the outer housing 26 (Landau '823; col. 4, lines 1-17). However, the "inner housing" (fluid cylinder 32) does not move axially away from the nozzle 30. Here, the fluid cylinder 32 is axially fixed with respect to nozzle 30, nozzle outlet 40 and fluid inlet 42. Additionally, as mentioned above, the outer housing 26 of Landau '823 lacks cooperating guide means and a nozzle.

Piston Cylinder 62/62a as "Outer Housing"

Gas Cylinder 72 as "Inner Housing"

During the interview, an alternative interpretation of Landau '823 was put forward by the Examiner. In particular, the Examiner suggested that the piston cylinder 62/62a be considered the "outer housing" and the gas cylinder 72 be considered the "inner housing." It respectfully submitted that with this interpretation, the Landau '823 device still does not anticipate Claim 1. Here, it is noted that Claim 1 recites that the inner cylinder is disposed at least partly within the outer cylinder. Moreover, Claim 1 recites that the inner cylinder and the outer cylinder include cooperating guide means. In Landau '823, the gas cylinder 72 is not at least partly within the piston cylinder 62/62a. Additionally, there are no cooperating guide means between the gas cylinder 72 and the piston cylinder 62/62a that guides axial movement of the inner housing to enable a dose of medicament to be drawn into the nozzle. Indeed Landau '823 specifies that the

gas cylinder and the piston cylinder 72 are axially fixed with respect to one another (Landau '823; col. 3, line 57).

Fluid Cylinder 32/85 as "Outer Housing"

Gas Cylinder 72 or Piston 60 as "Inner Housing"

It is noted that, if the fluid cylinder 32/85 is to be considered an outer housing (as indicated by the Office Action), it is respectfully submitted that the device disclosed by Landau '823 still does not anticipate the claimed invention. In particular, the Landau '823 device does not disclose an inner housing located at least partly within the outer housing, and a cooperating guide means on the inner and outer housing. More particularly, it is noted that the fluid cylinder 32/85 includes a nozzle 30 and a guide means 80. However, the guide means 80 does not cooperate with a guide means disposed on those components which are indicated by the Examiner as being an "inner housing." In particular, in the Office Action the Examiner has indicated that the gas cylinder 72 and/or the piston 60 are to be considered as the "inner housing." In contrast to the inner housing of the claimed invention, neither the gas cylinder 72 nor the piston 60 has a cooperating guide means or is located at least partly within the "outer cylinder."

Fluid Cylinder 32/85 as "Outer Housing"

Piston Cylinder 62 as "Inner Housing"

Additionally, with the fluid cylinder 32/85 considered the "outer housing," if it is argued that the piston cylinder 62 is to be considered the "inner housing," it is observed that the piston cylinder 62 is not disposed at least partly within the fluid cylinder 32/85. On the contrary, the fluid cylinder 32/85 is located at least partly within the piston cylinder 62.

Piston Cylinder 62 as "Outer Housing"

Fluid Cylinder 32/85 as "Inner Housing"

Furthermore, the device disclosed by Landau '823 does not anticipate the claimed invention if the piston cylinder 62 is designated as the "outer housing" and the fluid cylinder 32/85 is designated as the "inner housing" because Claim 1 recites that the outer housing has a nozzle formed thereon. In the interview, the Examiner indicated the possibility of asserting this interpretation of Landau '823 in combination with an assertion that it would be obvious to modify Landau '823 to include a nozzle on the "outer cylinder" (in this case the piston cylinder). It is respectfully submitted that this modification would render the Landau '823 device inoperable. In particular, the Landau '823 device includes a variable volume reservoir 38, which is adjusted by a movement of a component (fluid cylinder 32) that includes the nozzle 30. Accordingly, modifying the Landau '823 device to include the nozzle 30 on an "outer cylinder" would prevent the volume of the reservoir 38 from being adjusted.

It can also be seen that there are significant structural differences between Landau '823 and the claimed invention. For example, it is observed that the Landau device is very complex in construction and therefore likely to be relatively expensive. As indicated in Claim 1 of Landau, only the nozzle is disposable and the main part of the device is reusable. (See last sentence of the abstract; *i.e.* "after injection the nozzle can be removed and replaced for each new use of the device".) In contrast, the claimed invention is an entirely disposable device, as specified in Claim 1.

In summary, the Landau '823 device does not disclose at least:

- medicament drawn into the nozzle through the nozzle outlet;
- cooperating guide means between an outer housing having a nozzle and an inner housing disposed at least partly within the outer housing;
- an inner housing selectively axially moveable away from the nozzle outlet;

In order for a rejection under 35 U.S.C. § 102 to be proper, each and every element as set forth in a claim must be found, either expressly or inherently described in a single prior art reference. (MPEP § 2131.) It is respectfully submitted that Landau '823 does not disclose each and every element as set forth in Claim 1, as amended. Consequently, the invention claimed in Claim 1 is not anticipated by Landau '823. Dependent Claims 2-16, 23, 28 and 29 are all dependent upon Claim 1 and are also not anticipated for the reasons given above.

Moreover, a number of the dependent claims recite additional patentable subject matter. For example, Claim 4 depends from Claim 2, and recites that the "dose indication comprises an audible indication of the dose." This feature does not appear in the cited references. There is no disclosure by the cited prior art references of an audible indication of the dose as claimed. Accordingly, Claim 4 should be allowed for at least this additional reason.

Claim 5 recites that the "guide means comprises a substantially helical groove on said outer housing and a corresponding protrusion on said inner housing." As specified by Claim 1, the cooperating guide means enable a desired dose of medicament to be drawn into the nozzle ready for injection. The cited references do not teach, suggest or describe guide means with a helical groove to enable medicament to be drawn into the nozzle of an injection device. Accordingly, for at least this additional reason, Claim 5 should be allowed.

Claims 6-10 generally depend from Claim 5, and therefore should be allowable for this additional reason. In addition, Claim 6 recites that the protrusion of the guide means "comprises a substantially helical arrangement of discrete teeth, having pits there between." There is no such disclosure in the Landau '823 reference or other cited references. The Landau '823 reference, in particular, discloses only conventional threads 80. (Landau '823; col. 4, ln. 1-10) Claim 7 further recites that the injection device comprises "an indication of the dose of medicament which is drawn into the device and a flexible indexer tab which can ride over said teeth in order to provide said dose indication." Landau '823 and other cited references do not disclose any component which anticipates this claim element. Accordingly, for at least these additional reasons, Claim 7 should be allowed.

Claim Rejections - 35 U.S.C. § 103(a)

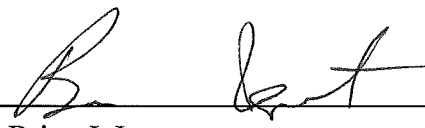
In order to establish a *prima facie* case of obviousness under § 103, there must be some suggestion or motivation to modify the reference or to combine the reference teachings, there must be a reasonable expectation of success, and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.) However, all of the claim elements cannot be found in the cited references, whether those references are considered alone or in combination. Accordingly, reconsideration and withdrawal of the rejections of the claims as anticipated by or obvious in view of the cited references are respectfully requested. Moreover, it is noted that if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). See MPEP §2143.03. Accordingly, it is respectfully submitted that the Examiner's obviousness rejection is moot in light of the arguments presented above. In particular, Claims 17-22 and 24-26 all depend from allowable Claim 1, and are therefore allowable.

Furthermore, it is also observed that there is no reason why the skilled reader would choose to combine the teachings of Landau '823 with Landau '030. It can be seen that the two disclosed devices are entirely different from one another in construction and operation and there is no motivation to adapt Landau '823 to include components of Landau '030. It is not clear which features of Landau '030 the Examiner considers to be equivalent to the fingered collet (Claim 16) and the lock sleeve (Claim 17) of the present invention. For example, the bushing 18 and locking body 20 of Landau '030 do not comprise "a lock sleeve surrounding said retention elements to prevent radial outward displacement thereof", as required by Claim 17. If, instead, the Examiner considers the gas seal 24 and sleeve 26 of Landau '030 to be "a lock sleeve" and the "retention elements" respectively, the interaction of these components cannot be made to fit the wording of claims 16 and 17, notwithstanding the inclusion of the limitations of Claim 1.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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